

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

PATTI JO GRAW,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 4:25-CV-01033 RWS
	)	
ELI LILLY AND COMPANY, et al.,	)	
	)	
Defendants.	)	

**MEMORANDUM AND ORDER**

This matter comes before the Court on the motion of Plaintiff Patti Jo Graw for leave to proceed in forma pauperis. ECF No. 2. Having reviewed the motion, I find that it should be granted. *See* 28 U.S.C. § 1915(a)(1). Furthermore, after reviewing the complaint, ECF No. 1, the Court will direct Plaintiff to show cause within twenty-one (21) days of the date of this Order as to why this action should not be dismissed for lack of subject matter jurisdiction. *See* Fed. R. Civ. P. 12(h)(3).

**The Complaint**

Plaintiff Patti Jo Graw, a citizen of the State of Missouri, is a self-represented litigant who filed the instant civil action against Defendants Eli Lilly and Company and Study Metrix Research, LLC for purported injuries she received after participating in a clinical trial from August 2023 through December 2023 for the diet and diabetic drug Retatrutide, referred to in the study documents attached to her

complaint as drug LY3437943. Plaintiff alleges that because of taking the diet and diabetic drug, she suffered severe medical consequences, including debilitating nausea, excessive vomiting, critically low potassium levels, multiple emergency room visits, hospitalizations, and the potential for a gallbladder removal. Plaintiff seeks compensatory and punitive damages in this action.

Eli Lilly is incorporated and has its principal place of business in the State of Indiana, according to several of its own filings in federal court. *See, e.g., Eli Lilly and Co. v. Becerra.*, No. 1:24-cv-03220 (D.C. 2024). According to the Missouri Secretary of State, Study Metrix Research, LLC was organized in March 2016 and has two individual members: Timothy Smith and Mitzi Sutton. An LLC's citizenship is based on the citizenship of each of its members. *E3 Biofuels, LLC v. Biothane, LLC*, 781 F.3d 972, 975 (8th Cir. 2015) (citation omitted). According to Study Metrix's Articles of Organization, Sutton is a citizen of Missouri and Smith is a citizen of Illinois.

Plaintiff asserts that she is bringing the present action pursuant to this Court's diversity jurisdiction. *See* 28 U.S.C. § 1332. She pleads claims under Missouri state law for negligence, medical malpractice, lack of informed consent, intentional infliction of emotional distress, and reckless infliction of emotional distress. In her complaint, Plaintiff additionally states the following: "Alternatively, jurisdiction is

proper under 28 U.S.C. § 1331 [federal question jurisdiction] due to questions arising under federal law, including violations of FDA clinical trial regulations.”

Plaintiff claims that Defendants have violated 21 C.F.R. §§ 50, 56 and 312.<sup>1</sup> However, courts have long recognized that agency regulations cannot themselves “conjure up a private cause of action that has not been authorized by Congress.” *Alexander v. Sandoval*, 532 U.S. 275, 291 (2001); *see also Smith v. Dearborn Fin. Servs., Inc.*, 982 F.2d 976, 979 (6th Cir. 1993) (“[F]ederal regulations cannot themselves create a cause of action; that is a function of the legislature.”); *Fed. Defs. of New York, Inc. v. Fed. Bureau of Prisons*, 954 F.3d 118, 129 (2nd Cir. 2020); *Smith v. Dearborn Fin. Services, Inc.*, 982 F.2d 976, 979 (6<sup>th</sup> Cir. 1993); *Stewart v. Bernstein*, 769 F.2d 1088, 1092–93, n.6 (5<sup>th</sup> Cir. 1985). And there is no indication that any of the regulations proposed by Plaintiff have a private right of action.

### **Discussion**

Subject matter jurisdiction refers to a court’s power to decide a certain class of cases. *LeMay v. U.S. Postal Serv.*, 450 F.3d 797, 799 (8th Cir. 2006). “Federal courts are not courts of general jurisdiction; they have only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress

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<sup>1</sup> Under the Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, prescription drug manufacturers must gain approval from the United States Food and Drug Administration before marketing any drug in interstate commerce. 21 U.S.C. § 355(a). Title 21 section 50 of the Act relates to the protection of human subjects.

pursuant thereto.” *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541 (1986); *see also Gunn v. Minton*, 568 U.S. 251, 256 (2013) (“Federal courts are courts of limited jurisdiction, possessing only that power authorized by Constitution and statute.”). The presence of subject matter jurisdiction is a threshold requirement that must be assured in every federal case. *Kronholm v. Fed. Deposit Ins. Corp.*, 915 F.2d 1171, 1174 (8th Cir. 1990); *see also Sanders v. Clemco Indus.*, 823 F.2d 214, 216 (8th Cir. 1987) (“The threshold requirement in every federal case is jurisdiction and we have admonished the district court to be attentive to a satisfaction of jurisdictional requirements in all cases.”). As such, the issue of subject matter jurisdiction may be raised at any time, by any party or the court. *Gray v. City of Valley Park, Mo.*, 567 F.3d 976, 982 (8th Cir. 2009).

The Court has jurisdiction to hear cases involving the Constitution, laws, or treaties of the United States under 28 U.S.C. § 1331, and the Court can hear cases where diversity jurisdiction exists under 28 U.S.C. § 1332. *See Auto-Owners Ins. Co. v. Tribal Ct. of Spirit Lake Indian Rsrv.*, 495 F.3d 1017, 1020 (8th Cir. 2007) (finding subject matter jurisdiction is lacking if neither diversity of citizenship nor federal question jurisdiction applies); *McLaurin v. Prater*, 30 F.3d 982, 984–85 (8th Cir. 1994) (noting Congress has directed that district courts shall have jurisdiction in both federal question and diversity cases).

Under 28 U.S.C. § 1332, the Court has diversity jurisdiction over cases *where the all the parties reside in different states* and where the amount in controversy exceeds \$75,000. The amount in controversy is to be ascertained from the complaint itself. *Horton v. Liberty Mut. Ins. Co.*, 367 U.S. 348, 353 (1961).

Here, it does not appear from Plaintiff's complaint that either federal question jurisdiction or diversity jurisdiction exists. First, although Plaintiff claims that Defendants violated several regulations relating to the Federal Drug Administration—namely 21 C.F.R. §§ 50, 56 and 312—she has not enumerated in her complaint how each of these regulations was violated by Defendants. *See Thomas v. United Steelworkers Local 1938*, 743 F.3d 1134, 1139 (8th Cir. 2014) (“Under the well-pleaded complaint rule, a federal question must exist on the face of the plaintiff's properly pleaded complaint in order to establish federal question subject matter jurisdiction.”). Additionally, Plaintiff indicates in the complaint that she is only pursuing Missouri state law claims of negligence, medical malpractice, lack of informed consent, intentional infliction of emotional distress, and reckless infliction of emotional distress. These claims cannot establish federal question jurisdiction. And as noted above, Plaintiff may not create a cause of action based on the Code of Federal Regulations if Congress has not provided a private right of

action.<sup>2</sup> There is no indication that Congress has created a private right of action for any of the enumerated regulations.

Although Plaintiff appears to wish to pursue this matter under the Court's diversity jurisdiction statute, both she and Sutton (one of the owners of the LLC) are citizens of Missouri. Thus, she cannot bring this action under 28 U.S.C. § 1332. As such, Plaintiff has failed to show a basis for this Court's jurisdiction.

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<sup>2</sup> Plaintiff cites to 21 C.F.R. § 50.20 in support of a private cause of action to enforce her informed consent rights. 21 C.F.R. § 50.20 is an agency rule that provides the following:

Except as provided in §§ 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

As explained by multiple courts, “21 C.F.R. § 50.20 does not create a private right of action . . . .” *Mongiello v. Hochul*, No. 22-CV-116-LJV, 2023 WL 2307887, at \*12 (W.D.N.Y. Mar. 1, 2023) (citing 21 C.F.R. § 50.1); *DeJean v. Kelly*, No. 8:22-CV-0461-KKM-TGW, 2022 WL 3345329, at \*2 (M.D. Fla. Aug. 12, 2022), *appeal dismissed*, No. 22-13048-JJ, 2022 WL 17568522 (11th Cir. Nov. 3, 2022) (“[The plaintiff's] other two claims for payment . . . and for a violation of 21 C.F.R. § 50.20 likewise fail because they are not recognizable claims.”); *Garfield v. Middle Tenn. State Univ.*, No. 3:21-CV-00613, 2021 WL 5770877, at \*3 (M.D. Tenn. Dec. 6, 2021) (“The regulation cited by Plaintiff, 21 C.F.R. § 50.20, explains the general requirements for informed consent by human test subjects in clinical trials.”)

### **Order to Show Cause**

As discussed above, Plaintiff has not adequately provided a basis for this Court's jurisdiction as she has not adequately indicated that her complaint is based on either federal question or diversity jurisdiction. *See* Fed. R. Civ. P. 12(h)(3). Therefore, Plaintiff will be ordered to show cause within twenty-one (21) days of the date of this Order as to why this case should not be dismissed for lack of subject matter jurisdiction. Failure to comply with this Order will result in the dismissal of this action without prejudice and without further notice.

  
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RODNEY W. SIPPEL  
UNITED STATES DISTRICT JUDGE

Dated this 15th day of July 2025.